



CASE QA0239A CIP

1624  
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1624

MORIARTY ET AL.

Examiner: V. Balasubramanian

APPLICATION NO: 09/891,750

FILED: JUNE 26, 2001

FOR: N-HETEROCYCLIC INHIBITORS OF TNF-ALPHA EXPRESSION

Assistant Commissioner for Patents  
Washington, D.C. 20231

AMENDMENT

Sir:

In response to the Office Action mailed May 18, 2004, having a one-month shortened statutory time set to expire on June 18, 2004, please enter the Amendments below and consider the following Remarks. With regard to the amendments below, for the Examiner's convenience a complete set of claims now pending is provided, on the understanding that the amendments filed on July 30, 2003 have been entered. Thus, the below amendments are further to those submitted on July 30, 2003.

| FEE VALUE<br>ACCOUNTABILITY |                    |
|-----------------------------|--------------------|
| DEPOSIT ACCOUNT NO.         |                    |
| 19                          | 3880               |
| FEE<br>CODE                 | VALUE<br>FURNISHED |
| 1201                        | 172                |
|                             |                    |
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Moreover, the cases establish that particularly in the area of pharmaceuticals, the Examiner is required to consider the compounds' biological properties in assessing the obviousness of the claims. For example, in *In re Wagner*, 371 F.2d 877, 152 USPQ 552 (C.C.P.A. 1967), the court reversed a PTO conclusion of obviousness. There, the claims recited benzimidazole derivatives substituted with at least one lower alkyl group at two specific positions. The prior art taught benzimidazole derivatives having no substituents or bearing dimethyl substituents at two *other* positions of the ring. On appeal, the CCPA pointed out that there were eleven possible locations for placement of the methyl substituents. *Id.*, 152 USPQ at 559. It specifically rejected the PTO's finding that "the modification of a compound by the addition of one or more methyl groups is well known and thus obvious," stating that such general statements cannot support legal conclusions of obviousness. *Id.* at 883-84, 152 USPQ at 559. The Board erred, the court found, *by failing to take into account biological or pharmaceutical properties of the compounds.* *Id.* at 881, 152 USPQ at 557.

As indicated by *In re Wagner*, it is well known in the field of pharmaceuticals that small changes can have dramatic effects on biological activity. *See also Kawai*, 178 USPQ 167, 173 (CCPA 1973) ("minor changes in chemical compounds can radically alter their effects on the human body").

For the foregoing reasons, applicant submits that the Section 103 rejections must be withdrawn.

#### FEES

Applicant has added four new claims. It is not believed a fee is due because a greater number of claims were previously canceled. However, in the event a fee is due, please charge same to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.


US application Serial No. 09/891/750  
Attorney Docket No. QA0239A-CIP

SUMMARY

In view of the foregoing, it is requested that the rejections be withdrawn and the case proceed to issuance. The Examiner is invited to contact the undersigned if it is believed prosecution could be expedited.

Respectfully submitted,

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